

Enw y Grŵp/ls-	
Bwyllgor:	Information Governance Sub-Committee (IGSC)
Name of Group:	
Cadeirydd y	
Grŵp/ls-Bwyllgor:	Huw Thomas, Director of Finance
Chair of Group:	
Cyfnod Adrodd:	2nd Fabruary 2022
Reporting Period:	2 nd February 2022

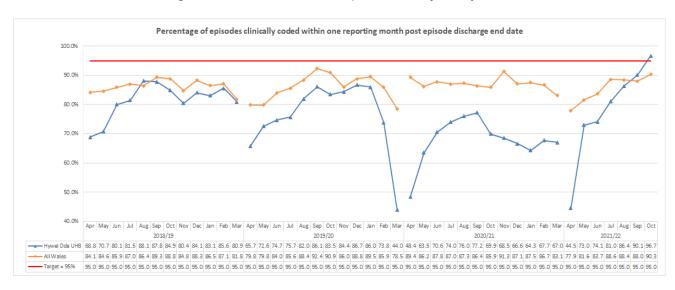
Y Penderfyniadau a'r Materion a Ystyriodd y Grŵp/ls-Bwyllgor:

Key Decisions and Matters Considered by the Group:

Clinical Coding Update

The Sub-Committee noted that Hywel Dda University Health Board (HDdUHB) clinical coding activity continued to improve for October 2021 and surpassed the 95% target with 96.7%. Over the past 2 months, the Health Board has been above the All-Wales average for the first time in a number of years and performance is continuing to improve. At the time of writing this report, provisional performance for November 2021 is anticipated to be 94.9%, however this is subject to confirmation. HDdUHB has ranked equal second place out of the 7 Welsh Health Boards for October 2021 performance, with only Powys Teaching Health Board and Betsi Cadwaladr University Health Board also achieving the 95% target for October 2021 activity.

The Sub-Committee noted the current clinical coding performance being above the Welsh average and that the clinical coding team are ahead of the planned trajectory.



The Sub-Committee requested that the reporting officer convey their thanks to the clinical coding team for the excellent progress made in coding percentage compliance.

Information Governance Documents

- **Corporate Records Management Policy:** The Sub-Committee noted the comments received and recommended that the policy be circulated for wider consultation.
- 190 Written Control Documentation Policy: The Sub-Committee approved the policy for onward submission to SRC for approval.

1/6

Corporate and Medical Records Storage Assurance

The Sub-Committee noted that the Information Governance team continues to undertake audits of record storage facilities, both internally and externally to the Health Board. As part of this work, a risk assessment for each facility will be undertaken.

HYWEL DDA RISK HEAT MAP								
	LIKELIHOOD →							
IMPACT ↓	RARE 1	UNLIKELY 2	POSSIBLE 3	LIKELY 4	ALMOST CERTAIN 5			
CATASTROPHIC 5								
MAJOR 4								
MODERATE 3	5		4		2			
MINOR 2								
NEGLIGIBLE 1								

There are a further 15 audits to be scheduled over the coming months and the Information Governance Team will be working with the Corporate Risk Team to ensure that these are reflected accordingly in the Corporate Risk Register.

Information Asset Registers

The Sub-Committee was requested to approve the following Information Asset Registers (IARs), following assurance by the Information Asset Owners Group (IAOG) and the Services' Lead Directors:

- Charities
- Occupational Therapy
- Physiotherapy
- Ceredigion County Services
- Public Health School Nursing

Information Governance Activity Report

The Sub-Committee received the Quarter 3 (Q3), 2021/22 report, noting the following:

- **Enquiries on Data Protection Framework** the number of enquiries (**110**) received during **Q3** is approximately 15.7% higher than the previous quarter (**95** enquiries), which is a large increase (61.8%) in comparison to **Q3** of the previous year 2020/21 (**68**).
- Personal Data Breaches the number of personal data breaches reported to IG during Q3 equated to 43, which is an increase of almost 48.3% compared to Q2 (29). It is important to note that of these 43 breaches, 9 were Near Misses. Most of the incidents fall within the following categories:
- Lost or stolen paperwork / hardware (4);
- Disclosed in error (14); and

- Unauthorised Access/Disclosure (18)
- Data Subject Requests –Health Subject Access Requests (SARs) are being reported differently for Q3. Information Governance is now authorising third party requests i.e. solicitors, insurance companies, Legal Power of Attorney's etc. in order to ensure that the Health Board is compliant with the Data Protection Act (DPA) 2018 and UK General Data Protection Regulation (GDPR). The number of Health SARs received totaled 230 during Q3, whereas the number of Data Subject Rights SARs equated to 104. There were 7 Corporate SARs received in Q3, a significant decrease compared with Q2 (12).
- **Training Compliance** IG training compliance has increased slightly with **Q3** recording on average **79.25**% in comparison to the previous quarter (on average **78.76**%). This represents the highest percentage compliance achieved in almost 3 years.
- National Intelligent Integrated Audit Solution (NIIAS) Monitoring In terms of alerts received, 64 Own Access Notifications were received during Q3, in comparison to the previous Q2 (59) and Q1 (53). During Q3, there were 43 Potential Family Access Notifications although there was 1 notification found not to be a relation. 6 of the triggers have been confirmed as legitimate accesses, and these accesses have been verified as legitimate by the Line Manager of the Service. The Committee should note that the above figures have increased as NIIAS is now monitoring additional systems and capturing information from Welsh Immunisation System (WIS), Children and Young Persons Integrated System (CYPrIS), and Cancer Information System Cymru (CaNISC).

- Information Commissioner Office (ICO) Notifications

Disappointingly, since April 2021, there have been 12 occurrences when a notification to the ICO has been required. High level discussion took place with more detailed discussion held in the IC session of the Sub-Committee meeting. The following table highlights the current notifications:

	Apr	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Open	1	0	1	1	1	1	1	1	7
Closed	2	2	1	0	0	0	0	0	5
Total	3	2	2	1	1	1	1	1	12

- Information Governance Newsletter

The Sub-Committee requested additional content to be included within the next Information Governance Newsletter. The content should include the number of ICO breaches, themes of said breaches, and case studies covering the consequences of breaching the data protection legislation.

Information Governance Newsletter 2 August 2021 Edition.

Data Protection Impact Assessments (DPIA) Update

The report submitted to the Sub-Committee summarised the activity in relation to DPIAs over the first three quarters of 2021/2022.

Month	Enquiry	Review of External DPIA	Not Needed	Withdrawn	Not Started	In Progress	Finalised and Signed Off	Totals per Month	Quarter 2021/22
April	2	1	1	-	32	2	1	39	
May	-	-	1	-	-	-	-	1	Q1 = 48
June	1	-	-	2	-	5	-	8	
July	5	-	1	-	-	-	2	8	
August	-	2	-	-	-	2	2	6	Q2 = 25
September	-	1	1	-	-	8	1	11	
October	-	2	3	-	-	6	1	12	
November	1	-	-	-	-	4	-	5	Q3 = 24
December	1	-	3	-	-	3	-	7	
Totals of Enquiry Type	10	6 3 Completed 3 In Progress	10	2	32	30	7	97	

The Sub-Committee enquired as to the high number in April 2022 that have not been started, and the reporting officer confirmed that 32 had been identified during the Information Asset Register Mapping where a DPIA was not present.

Information Governance Risk Register

The Sub-Committee noted the 2 risks contained in the Information Governance Sub-Committee Risk Register extracted from the Datix Risk Module on 18th January 2022. The risks have scored against the following 'impact' domains':

- Safety of Patients Staff or Public (1 risk)
- Business objectives / projects (1 risk)

Risk Ref	Date Risk Identified	Title	Directorate	Current Risk Score	Update from Sub-Committee
708	18/03/19	Inappropriate storage solutions associated with patient files / documents affecting Aberaeron, Cardigan and Tregaron Hospitals	Ceredigion	16	It was agreed that this Risk would be closed, and a new risk opened to cover the wider internal and external storage situation within the Health Board.
371	01/03/17	Inability to meet WG target for clinical coding and decision-making will be based on inaccurate / incomplete information	Finance: Digital	9	It was agreed that the Head of Information Services, would review the risk score given the current performance is above the Welsh average for the last 2 reporting periods

Cyber Security and Network and Information Systems (NIS) Directive Update

The Sub-Committee received a report providing a cyber security update on vulnerabilities, alerts, incidents, and Security Architecture work. The Sub-Committee was informed of the recent Price Waterhouse Cooper (PWC) report regarding the Ireland Health Service Executive (HSE), which was victim to a ransomware attack on 14th May 2021 and was subsequently unable to provide healthcare, which highlights the importance of investigating alerts. It was acknowledged that the HSE experience should be noted, and lessons learnt applied to other organisations. As the Health Board continues to develop its monitoring and response capabilities, it is expected that the number of alerts received will significantly increase.

In particular, the Sub-Committee noted:

- <u>Defender for Endpoint</u> Since December 2021, the Health Board has successfully onboarded Defender for Endpoint for all endpoints running an in-support version of Windows 10 in audit mode. Advantages of Defender for Endpoint include vulnerability scanning, software inventory, and advanced protection capabilities.
- Security Architecture The Cyber Security team continues to provide security architecture advice, ensuring designs follow security best practice and follow the requirements of the NIS regulations. It has become apparent, following engagement with some medical device vendors, that they do not follow industry best practices, which consequently introduces vulnerabilities to the network and introduces a risk of cyberattack for devices that could directly affect patient care.
- Email Phishing The Cyber Security team has recently purchased additional software
 which will allow the Team to undertake Phishing exercises. The upcoming work by the
 Cyber Security team will increase resilience against phishing emails and will include the
 introduction of staff awareness training, technical controls and processes to deal with
 phishing incidents.
- <u>Proactive Threat Detection</u> Third party supplier access to the network can introduce attacks against the network. There are recent cyber-attacks that highlight the requirement for robust third-party remote access. Attacks to note from 2021 include SolarWinds and Kaseya.
- <u>Vulnerability Detection</u> A worldwide critical vulnerability was disclosed in December 2021 and required a considerable amount of effort from the Digital team to remediate. Remediation is still ongoing whilst the team waits for vendors to update their software. Other software vulnerabilities that have been identified during scanning have started to be remediated. A total of 8 servers were identified and decommissioned in December 2021. Further servers have been identified for vulnerability scanning with work ongoing to onboard these identified servers onto the vulnerability management system. The Health Board currently has a total of 5,933 vulnerabilities, of which 590 are critical, 2,143 are high and 2,326 classed as medium. The remediation of end-of-life servers is currently being prioritised as these introduce the biggest risk to the network. However, these can also be the most difficult to remediate due to their use in the organisation.

The Sub-Committee thanked the Cyber Security team for their work, noting that Cyber Security capabilities have significantly progressed since the Cyber Security Senior Specialist and Cyber Security Specialists commenced in post. The Sub-Committee therefore agreed to the following next steps:

- Establishment of a reporting group to IGSC to take forward the Cyber Security workplan. This group will provide detailed updates to the In-Committee session of IGSC meetings.
- Each of the High alerts will be risk assessed and, if required, be included upon the Digital Risk Register.
- The development of a detailed improvement plan for the Cyber Assessment Framework.

Materion y Mae Angen Ystyriaeth neu Gymeradwyaeth Lefel y Pwyllgor Adnoddau Cynaliadwy:

Matters Requiring Sustainable Resources Committee Level Consideration or Approval:

- Due to the requirement to sign-off the Information Governance Toolkit before the next meeting, an extra ordinary meeting will be arranged with key members of the Sub-Committee to approve the toolkit prior to submission to the Sustainable Resources Committee.
- Approval of the Written Control Documentation Policy (190) (attached at Appendix 1).

Risgiau Allweddol a Materion Pryder: Key Risks and Issues / Matters of Concern:

- The wider strategic issue of the storage of records and boxes within external storage companies.
- Proposed establishment of a reporting group of the Sub-Committee to address the recommendations following the Network and Information Systems Regulation Cyber Assessment Framework.

Busnes Cynlluniedig y Grŵp/Is-Bwyllgor ar Gyfer y Cyfnod Adrodd Nesaf: Planned Group/Sub-Committee Business for the Next Reporting Period:

Adrodd yn y Dyfodol:

Future Reporting:

- Information Asset Owners and Information Asset Mapping Update
- Data Quality and Clinical Coding
- Information Governance Risk Register
- Information Governance Toolkit
- IG Training Strategy
- Update on Cyber Security / NISR
- Caldicott Register to be returned to the IGSC meetings
- Digital / IG Policies and Procedures

Dyddiad y Cyfarfod Nesaf:

Date of Next Meeting:

1st April 2022

6



Written Control Documentation Policy

FOR APPROVAL BY

SUSTAINABLE RESOURCES COMMITTEE

Policy information Policy number:

190

Classification:

Corporate

Supersedes:

All previous versions

Local Safety Standard for Invasive Procedures (LOCSSIP) reference:

List the LOCSSIP reference if applicable, if not state not applicable

National Safety Standards for Invasive Procedures (NatSSIPs) standards:

List the NatSSIP reference if applicable, if not state not applicable

Version number:

4

Date of Equality Impact Assessment:

5.10.2021

Approval information

Approved by:

Pending

Date of approval:

Pending

Date made active:

Pending

Review date:

Pending

1/18

Summary of document:

This policy describes the process for the development, adoption, review, approval, publication and implementation of all written control documents (WCD's). This policy ensures the organisations WCDs are in line with current legislation, guidance and evidence. WCDs can include policies, procedures, guidelines and strategies.

Scope:

This policy applies to all staff employed by the health board who are involved with the written control documentation development and review process.

To be read in conjunction with:

- 153 Equality Impact Policy and Procedure (opens in new tab)
- 173 Freedom Of Information Policy (opens in new tab)
- 193 Retention and Destruction of Records Policy (including Health Records) Version 2 (opens in new tab)
- 224 Information Classification Policy (opens in new tab)
- 307 Production of Patient and Carer Information Policy (opens in new tab)

Patient information:

Not applicable

Owning group:

Written Control Document Review Task and Finish Group

Executive Director job title:

Board Secretary

Reviews and updates:

- Version 1 New policy approved on 10th May 2011.
- Version 2 Revised policy to reflect new process for written control documentation approved on 24th May 2016.
- Version 3 Slight amendments Data Protection Act, approved on 26th June 2018.

Version 4 – Full review

Keywords

Policy, procedure, guideline, protocol, Standard Operating Procedure (SOP), Written control documents (WCD), summary approval report, Document Approval Form (DAF).

Glossary of terms

Written Control Document, WCD

A collective word for all policies, procedures, guidelines and strategies that the health board have put in place to ensure that the organisation is run effectively.

DAF

Document Approval Form

SBAR

Situation, Background, Assessment, Recommendations (Report)

Version 4 190 - Witten control documentation policy

Page 2 of 18

CWCDG

Clinical Written Control Documentation Group

Owner Group

The committee, sub-committee, group or department that has ownership and responsibility for each WCD.

WHC

Welsh Health Circular. These are health guidance issued to health boards by the Welsh Government.



Contents

Introduction	5,
Policy statement	5,
Scope	5,
Aim	5,
Objectives	5,
Types of written control documents	5,
Classification of Documents	6,
Identifying the Need for Developing, Adopting or Reviewing a WCD	7,
Steps in the development and approval process	8,
Publication of the WCD	12,
Dissemination of the WCD	13,
Monitoring of the WCD	13,
Reviewing the WCD	13,
People included in the WCD approval process	14,
Written control document system	16,
Responsibilities	16,
Deferences	17

10/24

Introduction

Hywel Dda University Health Board (health board) has a legal duty to ensure that the policies, procedures, or guidelines are in place. Written Control Documents are also known as WCDs. WCDs help ensure that the health board follows legislation, meets mandatory requirements, and provides services that are evidenced-based, safe and sustainable.

Having relevant, up to date and easy to follow WCDs minimises risk to patients, employees and the organisation. With this policy the health board provides a robust and clear WCD management system. This policy includes the arrangements that support the development, review, approval, publication and implementation of WCDs. This policy helps to achieve compliance with corporate and clinical governance standards.

Policy statement

This policy sets out what the organisation does to manage WCDs and how that is done. This policy supports the effective decision making and delegation process and provides a step-by-step process for staff to follow.

Scope

This policy applies to all staff who have the responsibility for the development and or review, publication and implementation of WCDs within their role. This policy applies to all health board WCDs both clinical and non-clinical.

Aim

This policy aims to describe the WCD process ensuring they are in line with current legal requirements and relevant to the service.

Objectives

To achieve this aim, the policy sets out the procedures for:

- The development and review of WCDs.
- The standard approach to WCDs including corporate style and templates.
- Completion of equality impact assessments to enable the identification and elimination of inequality.
- Approval of WCDs following the correct approval processes.
- The publication of approved WCDs, including the WCD system.

Types of written control documents

Definitions of the WCDs in use within the health board are:

Strategy

A strategy is defined as a long plan designed to achieve goals or objectives. A strategy is often a broad statement of an approach to achieving these desired goals or objectives and can be supported by written control documents.

Policy

A policy is a written directive from the Board which may be driven by statute or law, describing the broad approach or course of action that the health board is taking with an issue. Policies define the commitment of the health board and the obligations of individual staff. A policy is underpinned by evidenced based procedures and guidelines which must be adhered to.

Version 4 190 - Witten control documentation policy Page 5 of 18

5/18 11/24

A policy is health board wide and approved on behalf of the Board via the correct approval process.

Procedures

A procedure is a standardised method of performing tasks by providing a series of step-by-step actions on how to achieve a safe and effective outcome.

A procedure often sets out how a policy is to be achieved; however, procedures can also be a standalone document and must be adhered to.

Clinical procedures must be underpinned by evidence-based guidance from recognised bodies.

Guidelines

A guideline gives general advice and recommendations for dealing with a specific circumstance.

A guideline must be used in conjunction with your existing knowledge and expertise to ensure you take the right action in a specific situation.

A guideline often sets out how a policy is to be achieved however guidelines can also be standalone documents.

A clinical guideline is underpinned by evidence-based guidance from recognised bodies. Clinical guidelines should be followed to protect yourself and the organisation if an issue occurs.

Protocol

The health board considers this document as the same status as a procedure and should be referred to as a procedure.

Pathway

The health board considers this document as the same status as a guideline and should be referred to as a guideline.

Standard Operating Procedure

A standard operating procedure is either a procedure or a guideline and the appropriate template should be used.

Classification of Documents

Clinical

Clinical WCDs relate to the care and treatment of patients and offer an evidence-based approach to clinical decisions for patients with a given condition.

Corporate

Corporate WCDs relate to the management of the organisation and formulate the organisation's response to known situations and circumstances.

Version 4

190 - Witten control documentation policy

Page 6 of 18

Employment

Employment WCDs relate specifically to the management of employees (however defined) within the organisation. They are guidance on how a wide range of issues should be handled, incorporating a description of principles, rights and responsibilities for managers and employees.

Financial

Financial WCDs relate specifically to the financial controls within the organisation. They are a written source of guidance and incorporate a description of controls, processes and responsibilities for all managers and employees. These need to align to the Health Board's standing orders and Standing Financial Instructions. The governance of financial WCD is overseen by the Health Board's Finance committee. Financial WCD do not need require a DAF or to go through the global consultation process.

Identifying the need for developing, adopting or reviewing a WCD

The reason to develop a new, adopt or review an existing WCD can come from a variety of sources including:

- changes to legislation or national guidance,
- external reviews,
- audits,
- standardisation,
- clarify or improve working practices,
- to lessen an identified risk
- to adopt an all Wales WCD.

The managers and staff of a service are often best placed to recognise when a WCD is needed. One example is the development of a WCD following an investigation into an incident which includes recommendations on other controls to prevent a reoccurrence. This can also be because of an investigation into a complaint, litigation or external investigation, audit or report.

Most WCDs are developed internally for use within the organisation, occasionally a WCD needs to be developed jointly with another organisation. See joint policy example 395 – Section 136 – Mental Health Act, 1983 Mentally Disordered Persons found in public places (opens in new tab). This document brings together the Local Authorities, Police, Ambulance and other partner organisations.

Some WCDs are issued on an all Wales basis with the expectation of local adoption. These documents must also be subject to formal approval for use in the health board. Although the content of these documents cannot be amended it is for us to confirm how they will be implemented and monitored. If more specific local information and guidance is required to implement the All Wales document this will be contained in a local written control document.

When you discover a need for a new WCD or to amend an existing document, you must contact the Policy Co-ordination Officer before doing anything else. The Policy Coordination Officer will be able to provide advice and support about each stage of the process. You can contact the Policy Co-ordination officer via email at policies.hdd@wales.nhs.uk

You cannot develop or amend a document on your own, the document must be owned and overseen by the correct committee, sub-committee, group or department (known as owner group). The owner group must contain the expertise to advise on current legislation, guidance and evidence which affects the WCD. They must nominate a lead author who will handle ensuring that the process outlined in this

Version 4 190 - Witten control documentation policy Page 7 of 18

7/18

policy is followed. WCDs should always be developed and reviewed in collaboration with others to ensure that the final document is in line with current legislation, guidance and evidence. If not, this may delay the approval of the document.

Strategies and policies must be sponsored by the Executive Director who has responsibility for the relevant service or area the document relates to.

All Wales and joint WCDs must be overseen by the right committee, group or department who will nominate a lead to complete the approval process.

Steps in the development and approval process

Step 1 – Document Initial Assessment Form (DAF)

The first step in the WCD process is the completion of the Document Approval Form (DAF).

The DAF must be completed with the WCD for all documents except:

- Financial procedures as these are structured documents which link into our standing financial instructions.
- A department only or single profession WCD, which sets out the requirements for a specific department or professional group and does not have wider implications. For further advice contact the Policy Co-Ordination Officer.

The content of all Wales documentation cannot be changed; however, the form needs to be completed to look at how the content can be implemented.

The DAF is to aid the responsible person to be clear about the reasons for the document, and the potential impacts of it. It is best practice to consider these prior to developing or reviewing all WCDs.

The DAF specifically aims to ensure that: -

- The right type of document is developed.
- The WCD is developed, adopted or reviewed within the context of existing WCDs.
- There is a plan of involvement with interested parties who will be essential to the implementation of the WCD.
- Consideration is given to the possible wider implications of the WCD.

Using this form from the start will ensure that the development or review process is robust, efficient and prompt. This form also enables the Policy Co-ordination Officer to track all WCDs which are under development or review.

Following sign off by the committee, group or department who owns the WCD, the DAF should be sent to the Policy Co-ordination Officer.

For Clinical WCDs, the DAF must also be reviewed by the Clinical Written Control Documentation Group (CWCDG) to ensure it is right for the purpose and everyone will be consulted. A mentor from CWCDG will be appointed.

Financial WCD – The process of completing a DAF is not required.

Version 4

190 - Witten control documentation policy

Page 8 of 18

Step 2 - Format of your document

The development and review of a WCD requires proper planning and time for collaboration with others. This will ensure that the WCD is robust and meets the requirements of current legislation, guidance and evidence. It will also ensure that enough time to undertake the development process is allocated. A minimum of 6 months should be allowed from the completion of the DAF to final publication.

Once the type of document has been agreed, the correct template must be used to ensure that the information needed is contained within the document.

The templates and guidance on how to complete them are included as appendices to this policy. Using the template correctly will ensure the document is as digitally accessible as possible, and that it can progress to consultation stage. WCDs not following this format will not go on further in the process and will be returned to the author for correction.

The new digitally accessible templates can be found here on the developing a written control document page (opens in new tab)

All WCDs must follow the Digital Accessibility Standards which came into force for all public sector bodies in the United Kingdom on 23rd September 2018. The templates have been designed to comply with this, you must follow the guidance document when completing the template.

It is important that all WCDs are written so that they can be understood by all staff, to do this the document must be written with a reading age of between 8-12 years. All WCDs must be factual, evidence-based and concise.

Step 3 - Assessing for impact

Equality Impact Assessment (EqIA)

The impact of the WCD must be considered before starting its development or at the first stages of its review. Undertaking an equality impact assessment enables resources to be targeted effectively and can help to reduce health inequalities.

A first screening will need to be undertaken for all WCDs as this will show whether a full equality impact assessment is needed.

The EqIA process involves looking at the likely effects of this document both while it is being developed and while it is being implemented. Impact assessments apply to existing as well as new and proposed WCDs.

Impact assessments must be undertaken on relevant WCDs to ensure they follow the Equality Act 2010 and the Data Protection Act, General Data Protection Regulations 2016 and any later legislation.

The WCD author will need time to assess the document and make any required changes once the EqIA has been completed.

The impact assessment will be published along with the approved WCD.

Further information, guidance and support on EqIA completion is available here on the Equality, Diversity and Inclusion intranet page (opens in new tab).

Version 4

190 - Witten control documentation policy

Page 9 of 18

You can also contact the team via email on Inclusion.hdd@wales.nhs.uk.

Privacy Impact Assessment

Privacy Impact Assessments (PIAs) look at the privacy and data protection issues that may arise by the implementation of a WCD. This assessment ensures that the WCD does not breach the Data Protection Act, General Data Protection Regulations 2016 or any other related laws and guidance.

Ensuring WCDs are developed or reviewed with privacy in mind at the outset can lead to benefits which include:

- Potential problems are found at an early stage, this means addressing them early will often be simpler and less costly.
- Increased awareness of privacy and data protection across our organisation.
- Organisations are more likely to meet their legal obligations and less likely to breach regulations
- Actions are less likely to be privacy intrusive and have a negative impact on individuals.

A PIA can reduce the risks of harm to individuals through the misuse of their personal information. It can also help to design a more efficient and effective process for handling personal data. A first screening tool will need to be completed on all WCDs as this will show whether a full assessment is needed.

The Information Governance Team is available to help and recommend that staff complete the document and to answer any queries about the process. You can contact the team via email Information.Governance.hdd@wales.nhs.uk

<u>Further information on PIAs can also be viewed here on the Information Commissioners Office (ICO)</u> website (opens in new tab)

Step 4 – Collaboration with others

Compliance with legislation and regulations

All WCDs must follow legislative frameworks such as Consent, Deprivation of Liberties, Mental Capacity, Child and Adult Safeguarding, Data Protection, Welsh Language, Digital Accessibility, Equality and Fraud. To do this, the lead author must seek assurance from the relevant health board leads that the WCD adheres to the relevant legislation. Evidence of this assurance must be included in the SBAR which goes with the final draft WCD when presented to the Approving Committee, Sub-Committee or Group.

Interested Parties Involvement

WCDs must not be developed in isolation. At the start of the development, adoption or review process all interested parties named in the DAF, must be approached by the lead author. The early involvement of all interested parties ensures the WCD is fit for purpose and can be implemented and followed by all involved.

Interested parties can contribute to the content of the WCD and give approval of the sections which they handle or that will affect them. Interested parties must find any barriers which could obstruct the implementation of or compliance with the WCD. Any identified barriers must be resolved prior to the WCD being presented for approval.

Version 4

For clinical WCDs, the lead author must contact the Clinical Effectiveness Co-ordinator who will help with the identification of all relevant National Institute of Clinical Excellence (NICE) and Royal College Guidance. This guidance must inform and be referenced within the WCD.

Most clinical WCDs must include patient information leaflets as appendices when approved. Eido Healthcare or Welsh Risk Pool (WRP) approved alternative patient information leaflets must be used wherever possible. For more information you can click here to visit the Patient Experience intranet page (opens in new tab)

<u>Information on developing patient leaflets can be found here in 307 - Production of Patient and Carer Information Policy (opens in new tab)</u>

If you would like further information on patient leaflets you can email patient.experience.HDD@wales.nhs.uk

Comments and feedback received from interested parties must be collated and a record kept of the action taken; for example, if the comments were incorporated or not. This information must be included in the SBAR when the WCD is presented for approval.

Step 5 - Consultation

This is the final stage in the development, adoption or review process. This provides a further opportunity to interested parties who have already contributed and those who might have been inadvertently missed, to comment.

Consultation must be undertaken for all organisational strategies, policies, procedures and guidelines, which are multi-disciplinary or multi-agency. You can contact the Policy Co-ordination Officer for advice on this.

Consultation involves the WCD being placed onto the health board's intranet site for a minimum of two weeks. All members of staff are invited to comment on the WCD via the on-line form. The completed comment form is sent direct to the lead author for consideration and action.

Comments and feedback received from the consultation must be collated and a record kept of the action taken. This must be included in the SBAR which will go with the WCD when it is presented for approval.

Step 6 - Preparing your document for approval.

Before you are ready to send your WCD for approval you must ensure you have all the accompanying information completed.

- Equality Impact Assessment (EqIA).
- 2. Privacy Impact Assessment (PIA).
- 3. Interested parties' comments or approval.
- 4. If required, a full implementation plan.
- 5. SBAR which refers to all the above.

SBAR

All WCDs presented for approval must be accompanied by a SBAR which will provide assurance that the development or review of the WCD has been undertaken in line with this policy.

Version 4

190 - Witten control documentation policy

Page 11 of 18

The SBAR needs to: -

- Prove the development process has been robust and in line with this policy.
- Prove the last version of the WCD is in line with current legislation, guidelines and evidence and can be implemented.
- Include an assessment of the impact of the WCD, the EqIA and PIA.
- List the interested parties who have been involved in the development of the WCD and evidence their approval of the final WCD.
- Supply evidence that a wider consultation has taken place and include the record of comments received and actions taken.
- Supply details on how, and by whom, the WCD is issued and how you will ensure that this happens.
- Supply details on how, by whom and when the WCD will be implemented and whether a detailed separate implementation plan is needed. If it is, this must go with the SBAR
- Prove that there are processes in place to check the compliance with the WCD and show how they will be addressed as soon as possible.

Step 7 – Approval of your WCD

Approval of single department or profession WCDs

These WCDs relate to a single department, profession or staff group and there is no wider impact on the health board. Final approval of these documents can be provided by the department or service manager. These documents do not need to be recorded on the central database, but records must be kept at a local level. This is to ensure that there is a full history and document archive in line with the 193 – Retention and Destruction of Records Policy (opens in new tab)

Approval of all other WCDs

The Board has delegated approval of WCDs to its committee structure. WCD approval is included within the individual committee, sub-committee and group's terms of reference. All WCDs must be sent to the right approving committee, sub-committee or group for approval. You can find out more about which committees, sub-committees or groups approve which document by contacting the Policy Coordination Officer.

If an approved WCD needs to be amended or updated prior to the full formal 3-year review, contact the Policy Co-ordination officer for instructions.

Approval of urgent documentation without an equality impact assessment having been finalised. In exceptional circumstances only, a WCD without an EqIA can be approved. This must only be for a short interim period of 1-3 months only. This brief period is to give the author time to complete the equality process.

Once this urgent document has been approved an email must be sent to the lead author and copied to the line manager and executive lead. This email will confirm the short approval and make it clear that the document will be removed after that date. The WCD and all supporting documentation must go for approval to the next relevant group or committee meeting.

Publication of the WCD

Following approval, the last version of the WCD, plus its impact assessment documentation, must be sent to the Policy Co-ordinator within 5 working days.

Version 4

190 - Witten control documentation policy

Page 12 of 18

The Policy Co-ordination Officer will then:

- Upload the WCD and impact assessment documentation on the intranet or internet site as appropriate within the next 5 working days.
- Include the WCD in the daily global email sent out by the Communications Team.
- Include the WCD in the Freedom of Information Publication Scheme.

The intranet or internet page will be the primary location for all WCDs. This ensures that staff have access to the most up to date version. Staff should not upload duplicated versions of the approved WCDs but should link to the newest online version. All approved WCDs will be listed on the approved WCD page on the intranet or internet site as appropriate.

The lead author can arrange for a link to the document to be published within relevant newsletters and or other relevant sections of the intranet. Make sure that it is the link that is published and not a downloaded version of the WCD.

Dissemination of the WCD

The owner group is responsible for agreeing how, and by whom, the WCD is issued. They must also ensure that this is undertaken. As a minimum, the WCD must be issued to the relevant operational leads to implement the WCD locally.

In addition to the dissemination found within the scope, all WCDs are also issued, as relevant to Assistant Directors, Associate Medical Directors, and operational senior management. They will then act as appropriate.

Monitoring of the WCD

The owner group is responsible for ensuring that they check compliance with the WCD. They must ensure that any issues which are found are addressed as appropriate. This might result in the updating of the WCD. Correct monitoring will help ensure that the WCD stays in line with current legislation, guidance and evidence.

Reviewing the WCD

All WCDs must be reviewed every three years unless it has been reviewed within this time scale.

The owner group is responsible for ensuring the document is reviewed and stays in line with current legislation, guidance and evidence. They must review the WCD considering new or updated legislation and or guidance as they are published.

Extending review dates of the WCD

The Policy Co-ordination Officer will contact the owner group to let them know their document is due for review 9 months before the review date. The lead author, in conjunction with the owner group, is responsible for ensuring that the document is reviewed before the expiry date. If the expiry date will pass, the owner group must receive assurance that the current version of the WCD is still fit for purpose. The owner group must then agree an extension of up to a maximum of six months.

Version 4

190 - Witten control documentation policy

Page 13 of 18

Any significant changes to an existing WCD will require it to be re-approved by the approving owner group by following the WCD process.

Minor changes to an existing WCD

If the amendments are minor, then a version control document should be completed, and attached to a tracked-change Word version of the WCD. The version control document must be fully completed and approved by the owner group. The equality impact assessment must be checked to see if it requires updating in line with the changes. Documentation should be forwarded to the Policy Co-ordination Officer for uploading.

Significant changes to an existing WCD

Significant changes to an existing WCD must be undertaken in conjunction with key individuals and the owner group identified in the original SBAR. Amendments should be undertaken using tracked changes in Word for record keeping purposes.

The equality impact assessment must also be reviewed. The amended WCD must go out for global consultation as in the initial process.

A new SBAR should be completed prior to approval.

People included in the WCD approval process

Sub-committee, group or department who owns the WCD (known as the owner group)

The owner group is responsible for approving procedures and guidelines and recommending policies for approval to the approving committee, sub-committee or group.

The owner group is responsible for: -

- Ensuring the development or review of the WCD is undertaken within the timescale.
- Ensuring that it has the relevant knowledge and expertise within its membership to develop or review a WCD.
- Nominating and providing support to the lead author. The support person will be responsible for ensuring that the process outlined in this policy is adhered to.
- Signing off the DAF.
- Providing assurance to the approving committee, sub-committee or group via a SBAR that the following has been undertaken:
 - The developmental process has been in line with the WCD Policy.
 - The final version of the WCD complies with current legislation, guidance and evidence and can be implemented.
 - Agreement on how, and by whom, the document is disseminated and ensuring that this is undertaken.
 - Agreement on how, by whom, and when the WCD will be implemented and whether a detailed separate implementation plan is required.
 - There are mechanisms in place to monitor the compliance with the WCD and ensuring that any identified issues are addressed as soon as possible.
 - Ensuring that the WCD remains in line with current legislation, guidance and evidence throughout its lifetime.

Version 4

Lead author

The lead author will be identified by the owner group and will act as the nominated lead during the development or review of the WCD. The lead author should have the right level of knowledge, and experience to lead on the development of WCDs on behalf of the owner group. In particular, the lead author will be responsible for ensuring that each step of the WCD procedures has been followed.

The lead author, in conjunction with the owner group, is responsible for:

- Contacting the Policy Co-ordination Officer at the start for advice and support throughout each stage of the WCD development or review process.
- Identifying the scope and purpose of the document and completing the DAF before starting the
 development or review of the document.
- Identifying the interested parties, dependent upon the scope of the document and expertise required. These may include other specialist groups and committees, specialties, professional groups or services.
- Identifying and following the approval procedure for the WCD being developed or reviewed.
- Providing assurance to the approving committee, sub-committee or group that all relevant interested parties have contributed and given approval of the WCD.
- Where any issues cannot be resolved, the most senior appropriate individual must be notified before recommending the WCD for approval.
- Ensuring that the WCD is produced in line with current legislation, guidance and evidence.
- Ensuring that any potential negative impacts are considered throughout the development or review process. As a minimum, a screening for equality impact must be completed in line with this policy.
- Ensuring that privacy and data protection principles are considered by completing a Privacy Impact Assessment (PIA).
- Producing the SBAR which must accompany the final draft of the WCD.
- Developing or reviewing documents within the 6-month timeframe.

WCD approving committee

This will be the most appropriate committee with delegated authority from the Board and its sub committees.

All Wales or jointly developed policies must be formally adopted by the health board, via the appropriate approval committee, before being implemented in the organisation. These may require additional procedures to be developed to support implementation within the health board.

The approving committee through the SBAR must assure themselves that the following has been completed: -

- The development or review process has been robust and in line with the WCD Policy. The final
 version of the WCD is in line with current legislation, guidance and evidence and can be
 implemented.
- An assessment of the impact of the WCD including the EqIA and PIA.
- The SBAR lists the interested parties involved in the development of the WCD and their comments and approval of the final WCD have been considered.
- Evidence that wider consultation has taken place and records the comments received, and action taken.
- Agreement on how, and by whom, the document is disseminated and ensuring that this is undertaken.

Version 4

190 - Witten control documentation policy

Page 15 of 18

- Agreement on how, by whom, and when the WCD will be implemented and whether a detailed separate implementation plan is required.
- There are mechanisms in place to monitor the compliance with the WCD and ensure that any identified issues are addressed when identified.

Policy Co-ordination Officer

The Policy Co-ordination Officer will provide advice and support to authors throughout the WCD process.

The Policy Co-ordination Officer is responsible for:

- Managing the written control document system in line with statutory requirements outlined within the Public Records Act 1958.
- Providing secretarial support for the Clinical Written Control Documentation Group.
- Ensuring that this policy and process is followed and acting as the operational gatekeeper for all WCDs.
- Publishing WCDs on the staff intranet and internet sites as appropriate.
- Ensuring up to date guidance and documentation on the WCD process is accessible.

Written control document system

The WCDs which are approved within the health board are centrally managed through the Corporate Governance department. A WCD database is in place.

Once a WCD has been entered onto the database, approved and published on the intranet or internet then this should be regarded as the only official health board version by staff.

Where to find the approved WCDs

Intranet Pages:

Clinical WCDs can be found here on the Clinical Written Control Documents intranet page (opens in new tab)

<u>Financial WCDs can be found here on the financial written control documentation intranet page (opens in new tab)</u>

Internet page

Corporate and Employment WCDs can be found her on the written control document page of our website (opens in new tab)

Where a WCD has been replaced, the archived copy will be held by the Policy Co-ordination Officer but will no longer be available online. The health board is required to keep a record of all previously approved WCDs, for 30 years in line with WHC (2000) 071 for the Record and Records Management Policies

Each department or service which develops or reviews WCDs must set up their own WCD system. This must hold all current and out of date WCDs. All out of date WCDs must be kept for a period of 30 years.

Version 4

190 - Witten control documentation policy

Page 16 of 18

Responsibilities

Chief Executive

As Accountable Officer, the Chief Executive has overall responsibility for ensuring the health board has appropriate WCDs in place. These WCDs must comply with legislation, meet mandatory requirements, and provide services that are safe, evidenced-based and sustainable.

Nominated Director - Board Secretary

The Board Secretary is responsible for providing a robust and clear governance framework for the effective management of all WCDs, and compliance with this policy. Specifically ensuring that:

- A consistent approach and process for the development, approval, publication, implementation and management of WCDs meets statutory requirements is in place.
- There is an appropriate scheme of delegation in place for the approval of WCDs.
- There is a WCD management system in place.
- WCDs are available to the public to improve transparency and in accordance with the requirements of the Freedom of Information Act.

Senior Management

Senior management are responsible for:

- Ensuring that the WCD policy is adhered to by staff within their area of responsibility.
- Ensuring all staff have access to WCDs.
- Ensuring that all newly approved WCDs are distributed appropriately within their area of responsibility.

Department, service or ward management

Department, service or ward managers, through their supervisory structure, are responsible for:

- Ensuring that the WCD Policy is adhered to by staff within their area of responsibility.
- Contributing to the development of WCDs which may impact their area of responsibility
- Ensuring there is a robust documentation control system in place locally to ensure WCDs are readily available and accessible to staff.
- Ensuring that staff are working to the most up to date WCD.
- Ensuring that staff are aware of any new or reviewed WCDs and a process is in place to demonstrate that staff have read and understood the WCD.
- Ensuring that any new members of staff are made aware of the local WCD system at local induction. This must include how to access relevant WCDs and demonstrate that they have read and understood them.
- Ensuring their staff are competent to implement this WCD Policy.

All Staff

All staff are responsible for:

- Complying with this policy.
- Ensuring their practice is in line with all WCDs relevant to their area of work.
- Identifying any barriers to compliance with any WCD, and report this up through the appropriate structure, for example, competence or equipment.
- Identifying any changes in practice, guidance or legislation which requires a review of any WCD and report this up through the appropriate structure.

Version 4

References

- Cardiff and Vale University Health Board (2011) Management of Policies, Procedures and Other Written Control Documents Policy.
- Public Records Act 1958
- WHC (2000) 071 For the record and records management policies.

